



Health Services
LOS ANGELES COUNTY

June 19, 2007

**Los Angeles County
Board of Supervisors**

Gloria Molina
First District

Yvonne B. Burke
Second District

Zev Yaroslavsky
Third District

Don Knabe
Fourth District

Michael D. Antonovich
Fifth District

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

**APPROVAL OF AMENDMENT NO. 1 TO THE FIELD
ADMINISTRATION OF STROKE THERAPY-MAGNESIUM TRIAL
STUDY MEMORANDUM OF UNDERSTANDING
(All Districts) (3 Votes)**

IT IS RECOMMENDED THAT YOUR BOARD:

1. Approve and instruct the Director of Health Services, or his designee, to execute Amendment No. 1 to the existing Field Administration of Stroke Therapy-Magnesium (FAST-MAG) Trial Study Memorandum of Understanding (MOU), substantially similar to Exhibit I, with The Regents of the University of California on behalf of the University of California at Los Angeles (UCLA), to extend the current MOU term through December 31, 2007, with no net cost to the County.
2. Delegate authority to the Director of Health Services, or his designee, to sign any subsequent amendments to extend the FAST-MAG Trial Study MOU, on substantially similar terms, contingent upon extension of the Department of Health and Human Services National Institutes of Health (NIH) Grant awarded to UCLA, upon review and approval by County Counsel and the Chief Administrative Office, and notification to the Board.

PURPOSE/JUSTIFICATION OF THE RECOMMENDED ACTIONS:

The purpose of the recommended actions is to obtain approval to execute an amendment to the existing FAST-MAG Trial Study MOU between UCLA and the Department of Health Services (DHS) Emergency Medical Services (EMS) Agency to extend the County's participation in the federally-funded FAST-MAG trial study whose primary objective is to determine if prehospital treatment with magnesium sulfate administered by paramedics in the field improves the long-term functional outcome of hyperacute stroke patients. The Amendment to the MOU also provides operational changes to allow the parties to modify the research protocol in accordance with Federal regulations and provide a more effective method to oversee the study.

*To improve health
through leadership,
service and education.*

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Los Angeles, CA 90012

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www.ladhs.org

IMPLEMENTATION OF STRATEGIC PLAN GOALS:

These actions support the County's Strategic Plan Goal No. 1 for Service Excellence by enhancing the quality and availability of emergency medical care services countywide.

FISCAL IMPACT/FINANCING:

UCLA is the prime recipient of Grant No. 5 U01 NS044364-04 from the federal Department of Health and Human Services NIH (Attachment B) for the FAST-MAG trial study. DHS does not incur any costs associated with its continued participation in the FAST-MAG trial study.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS:

On December 14, 2004, the Board approved an MOU with UCLA for participation of EMS in the FAST-MAG trial study. In accordance with California Code of Regulations, Title 22, Division 9, Section 100146, paramedics are authorized to perform any prehospital emergency medical care treatment procedure(s) or administer any medication(s) on a trial basis when approved by the medical director of the local EMS agency.

Under terms of the MOU, paramedics screen all prehospital emergency medical care patients for study entry. Inclusion and exclusion criteria for study participation has been established and included in the FAST-MAG Clinical Trial Protocol developed by UCLA. Inclusion of study participants is subject to the approval of an on-call FAST-MAG physician-investigator, and consent by the patient or his or her authorized representative. The FAST-MAG trial study was set up to fund up to 1,298 patients with acute stroke to be identified in the field by licensed paramedics in Los Angeles County. However, as of February 2007, only 300 subjects had enrolled in the study. Extending the current MOU term will ensure that all potential FAST-MAG trial study patients in Los Angeles County are identified, offered enrollment in the study, and have access to treatment that may improve their long-term functional outcome.

The FAST-MAG Trial Protocols for Enrollment and Consent have been revised to become effective with the proposed extension period. A new section, 3.1, Enrollment by Explicit Informed Consent, outlines requirements for the enrollment of study participants who are competent or who have an on-scene legally authorized representative. Another new section, 3.2, Enrollment in Emergency Circumstances of Non-competent Patients Without Written Informed Consent, outlines requirements for the enrollment of study participants who are non-competent patients without on-scene authorized representatives. The parties are obtaining final approvals as required by federal law for this trial study. To the extent the regulatory authorities require further additions, and to allow for more flexibility for the parties to design and conduct the study to best achieve its outcome, DHS will now be authorized under the Amendment to make further changes to the protocol upon approval by County Counsel.

The current federal NIH Grant for the FAST-MAG trial study expires December 31, 2007. A renewal of the Grant is expected to be awarded to UCLA for a four-year period, effective 2008 through 2012.

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Attachments A and B provide additional information.

County Counsel has approved Exhibit I as to use and form.

CONTRACTING PROCESS:

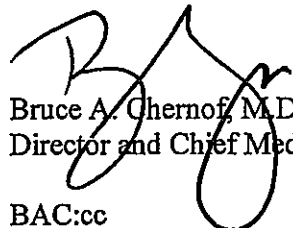
Not applicable.

IMPACT ON CURRENT SERVICES (OR PROJECTS):

Approval of this amendment and delegated authority to extend the MOU will enable DHS to continue participating in the FAST-MAG trial study to further evaluate the potential efficacy of intravenous magnesium sulfate administered by paramedics in the field to patients with acute stroke.

When approved, this Department requires three signed copies of the Board's action.

Respectfully submitted,



Bruce A. Chernof, M.D.
Director and Chief Medical Officer

BAC:cc
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Attachments (2)

c: Chief Administrative Officer
County Counsel
Executive Officer, Board of Supervisors
Auditor-Controller
Chair, Emergency Medical Services Commission
Health Care Association of Southern California
State Department of Health Services

SUMMARY OF MEMORANDUM OF UNDERSTANDING AMENDMENT

1. TYPE OF SERVICE

The Memorandum of Understanding (MOU) Amendment No.1 with The Regents of the University of California will extend the County's participation in the federally-funded Field Administration of Stroke Therapy-Magnesium (FAST-MAG) trial study through December 31, 2007.

2. AGENCY ADDRESS AND CONTACT PERSON

Sandra M. Perez
University of California at Los Angeles
Office of Contract and Grant Administration
FAST-MAG Clinical Trial Center
1072 Gayley Avenue
Los Angeles, California 90024-7325
Telephone : (310) 794-6155
E-mail: SMPerez@mednet.ucla.edu

3. TERM

The term of the MOU Amendment shall be effective July 1, 2007 through December 31, 2007.

4. FINANCIAL INFORMATION

The University of California at Los Angeles is the prime recipient of a grant from the federal Department of Health and Human Services National Institutes of Health for the FAST-MAG trial study. The Department of Health Services does not incur any additional costs associated with their continued participation in the FAST-MAG trial study.

5. PRIMARY GEOGRAPHIC AREA TO BE SERVED

Countywide.

6. APPROVALS

Emergency Medical Services:	Cathy Chidester, Acting Director
Contracts and Grants Division:	Cara O'Neill, Chief
County Counsel:	Edward A. Morrissey, Senior Deputy County Counsel
CAO Budget Unit:	Latisha Thompson

NOTICE OF GRANT AWARD

RESEARCH PROJECT COOPERATIVE AGREEMENT

Issue Date: 03/27/2007

Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Grant Number: 5 U01 NS044364-04
Principal Investigator: SAVER, JEFFREY L MD
Project Title: Field Administration of Stroke Therapy - Magnesium Trial

GRANT ANALYST
UNIV OF CALIFORNIA
OFC OF CONTRACT/ GRANT ADMIN
10920 WILSHIRE BLVD, STE 1200
LOS ANGELES, CA 900241406
UNITED STATES
Award e-mailed to: NIHAward@resadmin.ucla.edu

Budget Period: 01/01/2007 - 12/31/2007
Project Period: 09/30/2003 - 12/31/2007

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$1,000,000 (see "Award Calculation" in Section I) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 & 6306 and is subject to terms and conditions referenced below. Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of NIH support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in accordance with NIH policy. For additional information, please visit <http://www.iedison.gov>.

If you have any questions about this award, please contact the individual(s) referenced in the information below.

Sincerely yours,

King P. Bond, Jr.